eIRB Set to Debut on June 25, 2012

The day is almost here. The new IRB online submission system is set to debut on June 25, 2012. This new system is expected to improve the work flow process for submission, review and approval of IRB protocols. The new system will eliminate the submission of multiple forms as the initial protocol application for full board, expedited and exempt protocols have been combined into one form. In addition, this new system will eliminate the need to send applications separately to the Investigational Pharmacy, Pathology and the Department of Radiology, as these forms have been incorporated into eIRB and if you indicate that the protocol will involve the use of any one of these services, it will automatically be sent to them for review and approval. Finally, this new system will eliminate the need to submit SSRs for employees of WCMC, as the Conflicts System has been integrated with eIRB.

Some helpful hints when using the new system:

1. Remember, for currently active protocols, the IRB is adding limited information. Any missing information will need to be added the first time you are submitting either an amendment or continuing review of the protocol. Please remember to allow extra time the first time using eIRB for currently active protocols. Also, please remember to check the information that the IRB office has added for accuracy.

2. For new submissions, time can be saved by first filling out the current application forms and then copying and pasting into the new system, as the questions are very similar. This way, the protocol is easily edited, and can then be entered into the new system as a final version.

Further updates will be sent via broadcast e-mails, and final instructions and helpful hints will be posted on our website once the system is rolled out.

If you have any questions, please contact Rosemary Kraemer at 646-962-8200.

Important Information Regarding eIRB Go-Live

The IRB office will accept submissions for EXPEDITED review through June 13th. After June 13th, the submit2irb@med.cornell.edu listserv will be deactivated for any submissions. Between 6/13 and 6/25, Immediate Reports and short form consent requests should be sent to IRB@med.cornell.edu. No other submissions will be accepted.

Submissions for FULL BOARD review will be accepted through June 4th and will be reviewed either at the June 11th or June 25th IRB meeting. Submissions that require full Board review and are submitted after June 4th will be reviewed at the July 23rd IRB meeting.

ALL SUBMISSIONS AFTER 6/13 WILL BE REQUIRED TO USE eIRB STARTING JUNE 25TH. Please plan on allowing additional time for your first submission using eIRB, including submissions for already active protocols (e.g. Amendments, Continuing Reviews, acknowledgments, etc.). If you have any questions, please contact the IRB office at 646-962-8200.
CCTEC and Aptiv Solutions co-hosted a Medical Device Development Boot Camp™ on May 10, 2012 at Weill Greenberg Center. Attendees learned the keys to developing medical devices for commercialization from industry veterans, investors, patent advisors and the FDA. Presentations included obtaining patents and avoiding mistakes, navigating the regulatory maze for device registration, impact of the healthcare reform on medical device innovation, funding emerging medtech ventures, how much preclinical testing is needed, a dialogue to introduce adaptive designs in the medical device setting, safety surveillance for medical devices, development in the US, Europe and elsewhere, and case studies as examples of successes and lessons learned. After the presentations, attendees and speakers enjoyed drinks and hors d’oeuvres during a networking reception. For more information and to view photos from the event, visit http://www.cctec.cornell.edu/events/mddbootcamp/index.php.
IRB Acknowledgments and Immediate Reports

Principal Investigators are required to make Immediate Reports to the IRB in accordance with the Immediate Reporting Policy at http://weill.cornell.edu/research/research_integrity/institutional_review_board/irb_adv.html. The IRB also accepts Acknowledgment submissions and using the new eIRB system in the “Other Submissions” area you will be given the option to provide the IRB with either an Acknowledgment submission or an Immediate Report.

Immediate Reports vs. Acknowledgments

In order to provide the IRB with the appropriate submission type, it’s important to remember that Immediate Reports are pieces of information that involve risk or compliance issues like adverse events, protocol deviations, or FDA recommendations to change or halt the trial. The full policy on what qualifies as an Immediate Report can be viewed at http://weill.cornell.edu/research/research_integrity/institutional_review_board/irb_adv.html. By contrast, acknowledgments are items like Investigational Brochures that don’t change risks of participation, Notifications of Forthcoming Amendments, and information that does not generally reflect a risk or compliance issue requiring immediate action.

Should you have any questions about Immediate Reports and how they differ from Acknowledgment submissions, contact Lauren Odynocki, C.I.P. at lao2003@med.cornell.edu.

Grants and Contracts

Subject Injury Language in Clinical Trials

The section titled “POLICY/PROCEDURES FOR RESEARCH RELATED INJURY” in the Informed Consent Form (ICF) has to be reviewed by your OCTA Contracts Specialist for industry sponsored clinical trials after contract language is finalized.

Why?

OCTA is responsible for ensuring that the subject injury/research related injury section of the ICF is consistent with the subject injury language in the clinical trial agreement (CTA). CTAs are usually negotiated by a legal group at the sponsor, whereas the informed consent is reviewed by a clinical team—those two groups do not discuss contract language with each other.

Once the contract is finalized, an OCTA Contracts Specialist reviews the ICF to ensure that the subject injury section reflects the coverage that has been agreed to in the contract. Should the Contracts Specialist discover substantive discrepancies or conflicts between the CTA subject injury language and the ICF language, the PI, research team contact and IRB manager will be notified via email. Please always remember that the CTA subject injury language in these instances always prevails.

It is the responsibility of the principal investigator or research team to send the corrected/revised ICF to the sponsor for approval, immediately followed by an amendment to the IRB to revise the subject injury section in the informed consent form.

Why is this subject injury language important?
Subject provides protection to our research participants/volunteers in case they become ill or injured as a result of their participation in the trial. The language in the contract takes legal precedence over the ICF language, so it is important that the ICF and the CTA language are consistent. The ICF should provide an accurate explanation to subjects of what will happen and how their medical expenses will be covered if they get injured.

What should you do?
Please continue submitting the draft ICF as part of the original documents when you contact OCTA to start negotiations of the new contract. When you are close to obtaining IRB approval, please contact your Contracts Specialist and ask him or her to review the ICF subject injury language. Please make sure you provide the latest draft of the ICF. The Contracts Specialist can only review the subject injury section in the ICF after that section has been finalized by the sponsor in the CTA.

If you have any questions about this, please contact OCTA at (646) 962-8195 or email octa@med.cornell.edu.
Under expanded authorities, institutions have the ability to make certain adjustments to awards without prior approval from the NIH. For example, certain grants have the ability to automatically carryover unobligated funds from year to year. The diagram below should help guide you in determining what steps are required to have access to unobligated funds.

**Scenario 1**  
ACTIVE Grants under SNAP*

**Question A**: Do the terms and conditions of the NoA allow for automatic carryover authority?

Yes

**Question B**: Is the grant still ACTIVE?

Yes

**Question C**: Did the PI, as part of the grant progress report, notify the NIH of an estimated unobligated balance (including prior year carryover) to be greater than 25% of the currently year's total approved budget? [The total approved budget amount includes current year and any carryover from prior years of the project.]

Yes

**Question D**: If YES, to all the above AND the unobligated balance is greater than 25% of the total approved budget, please provide an explanation. No official request letter is required for ACTIVE NIH grants subject to SNAP guidelines.

**Scenario 2**  
INACTIVE Grants under SNAP

**Question A**: Do the terms and conditions of the NoA allow for automatic carryover authority?

Yes

**Question B**: Is the grant still ACTIVE?

Yes

**Question C**: Has the NIH ever been notified on the submitted FFR that an unobligated balance would be carried over?

Yes

**Scenario 3**  
ACTIVE Non-SNAP Grants

**Question A**: Do the terms and conditions of the NoA state that prior approval for carryover of unobligated balances is required by the NIH GMO?

Yes

**Question B**: Is the grant INACTIVE and all annual grant progress reports have been submitted by the PI?

Yes

**Scenario 4**  
INACTIVE Non-SNAP Grants

**Question A**: Do the terms and conditions of the NoA state that prior approval for carryover of unobligated balances is required by the NIH GMO?

Yes

**Question B**: Is the grant INACTIVE?

Yes

**Question C**: If YES, to Questions A & B and NO or Questions C & D, please contact Research Accounting for guidance and advisement.

* SNAP: Streamlined Non-competing Award Process (refers to Section 2.1 of the Non-Competing Continuation Progress Report guidelines for complete explanation of the SNAP Process. http://grants.nih.gov/grants/funding/phs2590/phs2590.9df)
Consultants, Subawardees and Vendors

When a portion of a project is completed by someone else outside of the lead institution there are different contractual relationships that establish obligations, terms and conditions and how the funds will be disbursed.

A consultant is an individual outside of the institution that receives a portion of grant funding if he or she:

✓ Is an expert advisor;
✓ Is paid via a fixed hourly/daily basis which includes travel, expenses and overhead;
✓ Uses his or her own equipment and materials and does not use facilities at his or her home institution;
✓ Is considered “work for hire”, whose work and intellectual property belong to the lead institution;
✓ Pay their own taxes on earnings;
✓ Is not employed by the lead institution; and
✓ Is not involved in the programmatic work of the project.

A subawardee is a subrecipient institution receiving a portion of grant funding if it:

✓ Has programmatic involvement identified as a separate scope of work and budget;
✓ Has its performance measured against whether the objectives of the project are met;
✓ Has responsibility for programmatic decision-making;
✓ Requires adherence to applicable program compliance requirements;
✓ Uses the grant funds to carry out the program at their organization;
✓ Has the right to publish project results;
✓ Has the option to develop patentable technology and IP resulting from the award; and
✓ There is a designated principal investigator.

A vendor is an entity receiving a portion of the grant funds if it:

✓ Provides goods and or services ancillary to the research project;
✓ Is paid by a flat fee;
✓ Provides similar goods or services to many different purchasers; and
✓ Is not involved in the programmatic work of the project.

The information above should help you determine which relationship fits your investigator or your collaborator and the type of agreement that should be issued.

For Consultants:

Outside consultants funded from WCMC sponsored projects, a Consulting Agreement is required. The Office of Clinical Trials Administration is responsible for review and approval of these agreements. WCMC’s template can be found here: http://weill.cornell.edu/research/forms_and_policies/grant_con.html and should be accompanied with a completed Independent Contractor Questionnaire and Checklists available from Finance. WCMC Investigators who are consultants on other institution’s projects can receive a courtesy review of their agreement by University Counsel. These agreements however are not institutional and are signed by the individual investigator.

For Subawardees:

The Grants & Contracts Office will review and approve incoming subaward agreements and issue outgoing subaward agreements once all internal documents are approved and the scope of work and budget are submitted.

For Vendors:

Please contact your department administrator as services are purchased through SAP in coordination with the Purchasing Department.

Should you have any questions or need guidance, please contact the Grants & Contracts Specialist assigned to your department.

Material Transfer Agreement News

To streamline the administrative process, a Scope of Work Form has been created specifically for Material Transfer Agreements. It looks and feels just like the standard Scope of Work Form but in addition, it (a) asks whether the project is a joint research collaboration and (b) requests the scope of work in layman’s terms.

The form is located at the following link: http://www.med.cornell.edu/research/forms_and_policies/grant_con.html.
New Conflicts of Interest Rules and Requirements Coming in August 2012

In response to the NIH’s 2011 release of new rules related to financial conflicts of interest, WCMC is in the process of updating its policies and procedures for conflicts of interest (COI). Complete information will be posted on the WCMC COI web page at [http://weill.cornell.edu/research/research_integrity/conflicts_management_program/index.html](http://weill.cornell.edu/research/research_integrity/conflicts_management_program/index.html) no later than August 24, 2012. Until then, here is some important information members of WCMC will want to know:

**Important Dates:**
- The 2011-2012 Annual Survey will close on July 14, 2012
- The 2012-2013 Annual Survey will open on July 16, 2012
- All NIH funded researchers must have completed the 2012-2013 Annual Survey by August 4, 2012
- All NIH funded researchers must have completed training on COI by August 24, 2012

**What to Expect in this Year’s Annual Survey:**
- The information requested is for the previous 12 months, rather than the current fiscal year
- Dollar ranges have been replaced by requests for specific dollar amounts
- Information requested is specifically related to one’s “institutional responsibilities”
- Excludes certain payments made by government agencies and institutions of higher education

**Overview of Key Changes in the NIH Rules for NIH funded researchers ONLY:**
- Drop in the dollar amount that could be considered significant from $10K to $5K, and any interest in non-publicly traded entities
- Requirement that reimbursed or sponsored travel be reported to WCMC
- Requirements for reporting information to NIH on identified conflicts
- Requirement that the policy and identified conflicts be made publicly available
- Requirement for training in conflicts of interest

**Where to Find More Information about the New NIH Rules:**
- NIH’s comparison chart highlighting key changes is available at [http://grants.nih.gov/grants/policy/coi/index.htm](http://grants.nih.gov/grants/policy/coi/index.htm)
  (scroll down to link to Summary of Major Changes)

**Who to Contact for Help:**
- Contact the conflicts staff for help at conflicts@med.cornell.edu or 646-962-8199

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**Environmental Health and Safety**

Anne-Marie Bakker has recently joined the EHS staff as the Senior Laboratory Safety Manager. She came to us from the San Francisco Bay area and has over 20 years of experience working in the Biotech industry. Her work included development and implementation of a wide range of safety programs for research and development laboratories.

In her position at Weill Cornell, Anne-Marie is responsible for the development and coordination of all laboratory safety programs. This includes education and outreach to the research community, safety plans for High Hazard Chemicals and general safety compliance. Anne-Marie’s current priorities are:

1. Bringing together the various safety programs (e.g. chemical, laser, radiation, biological, physical safety) and working with EHS staff to uniformly implement the safety program across the research departments.
2. Working with the FDNY to create a more consistent and reasonable interpretation of the laboratory regulations.
3. Keeping up with new research technologies, tools, and materials such as Nanotechnology and provide safety guidelines for working with new cutting edge research applications.
4. Increasing the availability of web-based training.

Please feel free to contact Anne-Marie at anb2063@med.cornell.edu or 646-962-5098 with any questions or to discuss any laboratory safety needs.
Cathy Stevens from the Department of Pediatrics recently presented at the May 23rd RCAC meeting on Best Practices for Effort Compliance Procedures at WCMC. In this presentation Cathy detailed how she handles Effort Compliance in a department with 13 divisions and over 100 academic and non-academic employees.

A few of her best practices are:

- She runs a SAP Activity Distribution report for the department and compares it against what is entered in ETS.
- Compares the department’s Coeus report against what is in ETS, this will help capture those instances when there is cost sharing and therefore would not appear in the SAP Activity Distribution report.
- Sits down quarterly with the investigators to review and sign off on their ETS worksheets.
- Has the investigator review their research associate's ETS worksheets and signs off.
- All changes in effort that is routed through RASP is changed in ETS as well.
- Cathy reviews each ERF and Grant application to check for those people in her department that she knows are reaching their effort cap.
## Grants and Contracts
**407 East 61st Street, 1st Floor, RR106, WCMC Box 89**

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Michelle Lewis, M.S.</td>
<td>mil2006</td>
<td>Director, Grants &amp; Contracts/OCTA</td>
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<td>Amy Zier, MBA, MSW</td>
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<td>Jennifer Cano</td>
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<td>Diana Gutierrez</td>
<td>dig2012</td>
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<td>Felicia Andrade</td>
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<td>Hilary Elliot</td>
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<td>Stephen Hunt</td>
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<td>Sr. Pre-Award Manager &amp; International Specialist</td>
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<tr>
<td>Bess Jensen</td>
<td>eaj2002</td>
<td>Research Administration, Business Analyst</td>
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<td>Patricia Kennedy</td>
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<td>Subaward Specialist</td>
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<td>Prathalad Raju</td>
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<td>CFR- Software Development Manager</td>
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<td>M. Eugenia (Gina) Vergara</td>
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<td>Ady Villegas-Estrada, PhD</td>
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<td>Barbara Lau</td>
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<tr>
<td>Mei Ling Acevedo</td>
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<td>Melanie Lebedowicz, JD</td>
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<td>Lee Stetson, JD</td>
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<td>Mary Kay Wolfe</td>
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<td>Kristen Rogers</td>
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<td>Yaritza Saavedra</td>
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<td>Allison Rodriguez</td>
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<td>Cynthia Franco</td>
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<td>Kristine Pangilinan</td>
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<td>Chad Davis</td>
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<td>Amenophis Faussett</td>
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<td>Manager, Conflicts and Compliance Programs</td>
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<td>Jennifer Akl</td>
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<td>Aron Arvai</td>
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<td>Lauren Odynocki</td>
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<td>Spencer Campbell</td>
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<td>Michael Murphy</td>
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<td>Mary Simmerling, PhD</td>
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<td>Brian Kelly, PhD</td>
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<td>Bruce Toman</td>
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